

## Specification Sheet 产品规格表

|                            |  |                            |
|----------------------------|--|----------------------------|
| Product name<br>产品名称       | Vitamin B12(Cyanocobalamin)<br>维生素 B12 (氰钴胺)   |                            |
| 原产地<br>Country of origin   | 中国<br>China  |                            |
| 有效期<br>Shelf-life          | 5 年<br>5Years  |                            |
| According as<br>检测依据       | USP38  |                            |
| Test items<br>检测项目         | Specifications<br>规格   | Test methods<br>检测方法       |
| Characters<br>性状           | Dark red,crystalline powder or dark red crystals. 深红色,结晶性粉末或深红色结晶  |                            |
| Identification<br>鉴别       | A: A <sub>361 nm</sub> /A <sub>278nm</sub> : 1.70~1.90<br>A <sub>361 nm</sub> /A <sub>550nm</sub> : 3.15~3.40                      | USP monograph              |
|                            | B : Meets USP requirements<br>符合美国药典要求   | USP monograph              |
|                            | C: HPLC:The retention time of the major peak of the sample solution corresponds to that of the standard solution.样品的主峰保留时间与标准溶液一致。 | USP monograph              |
| Loss on drying<br>干燥失重     | ≤10.0%   | USP monograph/<br>USP<731> |
| Assay<br>含量                | 97.0%~102.0%   | USP monograph              |
| Related substances<br>有关物质 | Total impurities ≤3.0 %  | USP monograph              |
|                            | 7 β ,8 β -Lactocyanocobalamin ≤ 1.0 %  | USP monograph              |
|                            | 34-Methylcyanocobalamin ≤2.0 %   |                            |
|                            | 8-Epi-cyanocobalamin ≤ 1.0 %   |                            |
|                            | 50-Carboxycyanocobalamin/32-Carboxycyanocobalamin /Any other unidentified impurity ≤0.5%   |                            |
| Residual solvent<br>溶剂残留   | Acetone ≤0.5 %<br>丙酮   | In house/(GC)              |
| Total plate count<br>总菌落数  | ≤1000 cfu/g  | USP<2021>                  |
| Yeasts and Molds<br>酵母菌和霉菌 | ≤100 cfu/g   | USP<2021>                  |
| E.coli<br>大肠埃希菌            | Negative/g<br>不得检出   | USP<2022>                  |
| Conclusion :<br>结 论 :      | The product complies with the specification of USP 38<br>产品符合美国药典 38 版   |                            |